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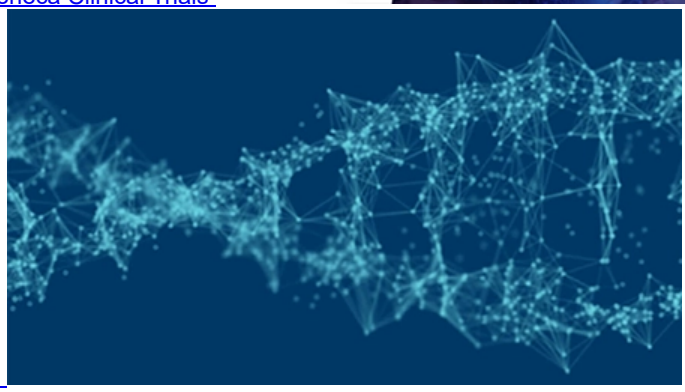
Featured website AstraZeneca Clinical Trials Featured website Open Innovation 

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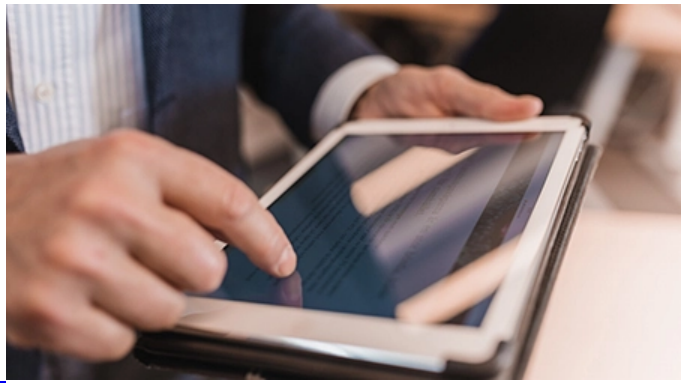


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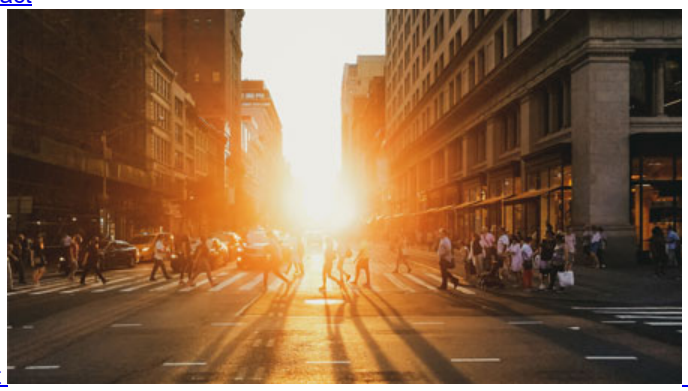

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# Evusheld (formerly AZD7442) long-acting antibody combination authorised for emergency use in the US for pre-exposure prophylaxis (prevention) of COVID-19

PUBLISHED 8 December 2021

**8 December 2021 21:00 GMT**

***Only antibody therapy authorised in US for pre-exposure prophylaxis***

***Pivotal phase III data showed robust efficacy and long-term protection with one dose in high-risk population***

AstraZeneca's *Evusheld* (tixagevimab co-packaged with cilgavimab), a long-acting antibody (LAAB) combination, has received emergency use authorisation (EUA) in the US for the pre-exposure prophylaxis (prevention) of COVID-19, with first doses expected to become available very soon.

The Food and Drug Administration (FDA) granted the EUA for *Evusheld* for pre-exposure prophylaxis of COVID-19 in adults and adolescents (aged 12 and older who weigh 40kg or more) with moderate to severe immune compromise due to a medical condition or immunosuppressive medications and who may not mount an adequate immune response to COVID-19 vaccination, as well as those individuals for whom COVID-19 vaccination is not recommended. Recipients should not be currently infected with or had recent known exposure to a person infected with SARS-CoV-2.

Myron J. Levin, MD, Professor of Pediatrics and Medicine, University of Colorado School of Medicine, US, and principal investigator on the PROVENT trial, said: “Millions of people in the US and around the world remain at serious risk for COVID-19 because their immune systems do not generate a sufficient immune response, even after receiving all recommended doses of vaccine. I am excited to offer my patients *Evusheld* as an easily-administered new option that provides long-lasting protection that could help them return to their everyday lives.”

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: “We are proud to play a leading role in fighting the COVID-19 pandemic and, with *Evusheld,* we now have the first antibody therapy authorised in the US to prevent COVID-19 symptoms before virus exposure, while also providing long lasting protection with a single dose. *Evusheld* neutralises all previous SARs-CoV-2 variants to date, and we are working quickly to establish its efficacy against the new Omicron variant. We thank our clinical trial participants, the investigators, scientists, and government agencies and our colleagues at AstraZeneca who have all contributed to the development of *Evusheld*.”

Brian Koffman, MDCM (retired), MS Ed, Co-Founder, Executive Vice President and Chief Medical Officer of the CLL (Chronic Lymphocytic Leukemia) Society, US, said: “One of the primary questions I keep getting asked by patients is ‘When can I hug my grandchildren again?’ As a physician and person with a weakened immune system, I am filled with hope now that *Evusheld* will soon be available to those who can’t count on vaccination alone to provide the protection they need.”

*Evusheld* is a combination of two long-acting monoclonal antibodies and is the only antibody therapy authorised in the US for COVID-19 pre-exposure prophylaxis and the only COVID-19 antibody delivered as an intramuscular dose (150mg tixagevimab and 150mg cilgavimab).

About 2% of the global population is considered at increased risk of an inadequate response to a COVID-19 vaccine.[1,2] About seven million people in the US are immunocompromised and may benefit from *Evusheld* for pre-exposure prophylaxis of COVID-19.[1,3,4] This includes people with blood cancers or other cancers being treated with chemotherapy, and those taking medications after an organ transplant or who are taking immunosuppressive drugs for conditions including multiple sclerosis and rheumatoid arthritis.[5-9]

The primary data supporting the *Evusheld* EUA are from the ongoing PROVENT Phase III pre-exposure prevention trial, which showed a statistically significant reduction (77% at primary analysis, 83% at median six-month analysis) in the risk of developing symptomatic COVID-19 compared to placebo, with protection from the virus continuing for at least six months. More follow-up is needed to establish the full duration of protection provided by *Evusheld*. Data from the Phase III STORM CHASER post-exposure trial and the *Evusheld* Phase I trial also supported the EUA. *Evusheld* was well-tolerated in the trials.

***Evusheld* and SARS-CoV-2 variants**
Studies are underway to provide information on the impact of the new Omicron variant (B.1.1.529) on *Evusheld.*[10,11] Of the Omicron binding site substitutions relevant to *Evusheld* that have been tested to date in preclinical assays, none have been associated with escape from *Evusheld* neutralisation.[10,11] *In vitro* findings demonstrate *Evusheld* neutralises other recent emergent SARS-CoV-2 viral variants, including the Delta and Mu variants.[10]

*Evusheld* is being developed with support from the US government, including federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority in partnership with the Department of Defense; Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, under Contract No. W911QY-21-9-0001.

AstraZeneca has agreed to supply the US government with 700,000 doses of *Evusheld*. The U.S. government has indicated that it plans to distribute these doses to states and territories at no cost and on a pro rata basis.

AstraZeneca is progressing with filings around the globe for potential emergency use authorisation or conditional approval of *Evusheld* in both COVID-19 prophylaxis and treatment.

**Notes**

***Evusheld***
*Evusheld,* formerly known as AZD7442 is a combination of two LAABs - tixagevimab (AZD8895) and cilgavimab (AZD1061) - derived from B-cells donated by convalescent patients after SARS-CoV-2 virus. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[13] and were optimised by AstraZeneca with half-life extension and reduced Fc receptor and complement C1q binding. The half-life extension more than triples the durability of its action compared to conventional antibodies and could afford up to 12 months of protection from COVID-19 following a single administration;[14-16] data from the Phase III PROVENT trial show protection lasting at least six months.[17] The reduced Fc receptor binding aims to minimise the risk of antibody-dependent enhancement of disease - a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[18] *Evusheld* is delivered as an IM dose of 150mg tixagevimab and 150mg cilgavimab administered in two separate, consecutive injections.

In August 2021, AstraZeneca announced that *Evusheld* demonstrated a statistically significant reduction in the risk of developing symptomatic COVID-19 in the PROVENT trial; efficacy was 83% compared to placebo in a six-month analysis announced on 18 November 2021. In October 2021, AstraZeneca announced positive high-level results from the *Evusheld* TACKLE Phase III outpatient treatment trial. *Evusheld* is also being studied as a potential treatment for hospitalised COVID-19 patients as part of the National Institute of Health's ACTIV-3 trial and in an additional collaborator hospitalisation treatment trial.

Under the terms of the licensing agreement with Vanderbilt, AstraZeneca will pay single-digit royalties on future net sales.

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**Contacts**
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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